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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/612,418

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JOHNSTON

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EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

09/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/612,418

Applicant(s)
Johnston et al.

Examiner
Ardin Marschel

Art Unit
1631



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-101 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-101 are subject to restriction and/or election requirements

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

~~PTO-152~~

Applicants are hereby notified that the required timing for the correction of drawings has changed. Applicants are required to submit Formal Drawings within the time period set in the attache Office communication. See 37 CFR 1.85(a). It is noted that the Drawings as filed are informal drawings. Formal drawings are NOW required. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-95, drawn to film layered detection articles with microchannels configured for uninterrupted fluid flow therein with the sample being drawn into the microchannels via spontaneous fluid transport plus methods of analysis utilizing same as well as methods of manufacturing of same, classified in Class 422, subclass 68.1. If this Group is elected, then the below summarized specie election is also required.

II. Claims 96-101, drawn to film layered microfluidic articles with microchannels configured for enhanced optical transmission through the film layer and methods of using same, classified in Class 422, subclass 82.05.

The inventions are distinct, each from the other because of the following reasons:

Each of the above summarized invention Groups are directed to distinct structural features which require a different and

distinct search. Group I requires search for film layered detection articles with uninterrupted microchannel flow as well as spontaneous fluid transport for sample entry whereas Group II is directed to enhanced optical transmission of the film layer in a similar but non-overlapping type of film layered detection article with microchannels for fluid flow. The search for each of these Groups is distinct and different and thus documents the undue search burden if they were searched together due to their different essential elements therein.

SPECIE ELECTION REQUIREMENT FOR GROUP I:

This application contains claims directed to the following patentably distinct species of the claimed invention: These species are distinct because they each add a feature to the detection article with different and distinct functions which each would require a separate and burdensome search to add to the search for the basic detection article as defined above.

Specie A: plurality of detection elements, e.g., claim 4

Specie B: coating on film layer, e.g., claim 10

Specie C: with a cap layer, e.g., claim 14

Subspecie C-1:

Transparent cap layer, e.g., claim 19

Subspecie C-2:

Cap layer with fluid control film with microchannels therein, e.g., claim 23

Specie D: plural microchanneled surfaces in film layer, e.g.,
claim 26

Specie E: plurality of fluid control film layers, e.g., claim 28

Specie F: assay reagent in detection element(s), e.g., claim 53

Specie G: Sample purification in detection element(s), e.g.,
claim 55

Specie H: additional detection element outside of the detection
zone, e.g., claim 65

Specie I: handle on article, e.g., claim 66

Specie J: plurality of acquisition zones, e.g., claim 67

Specie K: removable support layer, e.g., claim 78

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species (and Subspecie if Specie C above is elected) for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-3, 5-9, 13, 39-41, 58, 59, 72-75, 77, 81-90, and 92 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

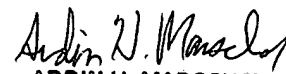
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

September 7, 2001


ARDIN H. MARSCHEL
PRIMARY EXAMINER